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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/702,037	10/27/2000	Peter Bennett Duff Whyte	U013032-6	8344

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William R. Evans
c/o Ladas & Parry
26 West 61st Street
New York, NY 25858

EXAMINER	
WARE, DEBORAH K	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
09/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/702,037	WHYTE, PETER BENNETT DUFF	
	Examiner	Art Unit	
	DEBBIE K. WARE	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-39,46-48,74 and 75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-39,46-48,74 and 75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 28-39, 46-48 and 74-75 are presented for examination on the merits.

Response to Amendment

The amendment filed June 2, 2008 and extension of time have been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Foreign Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Austraila on April 30, 1998. It is noted that applicant has filed on June 5, 2006, a certified copy of the patent application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 28-39, 46-48 and 74-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO/97/16977, AU-A-631136/94, , Clark et al, and Ballard et al (US 6,319,522), all cited of record in previous Office action of November 16, 2005.

Claims are drawn to methods of administering colostrum of which is prepared by ultrafiltration and spray drying, and also centrifugation and reconstituting steps can be

employed for the preparation of the colostrum. Each of the methods employ administering colostrum for changing physical work capacity of a subject.

WO 97/16977 (WO) teach administering effective amounts of compositions containing colostrum, see abstract and page 21, last two lines. Administering is carried out over a period of two weeks, see results of sample times, pages 10-12, Tables 3-6. The administering includes ingestion of a food composition (i.e. yogurt, see page 2, line 1) by a subject (i.e. coffee milk composition administered to a subject, see page 14, lines 5-20). The steps of preparing the colostrum are disclosed to encompass centrifugation to reduce bacteria (page 3, line 4), ultrafiltration (page 4, line 5), The colostrum is prepared so as to retain the immunoglobulin fraction containing antibodies and/or growth factors (see the abstract). The centrifugation is disclosed to take place at a temperature between 55 ^{o}C to 63 ^{o}C, (see page 3, lines 12-14). A heating step is disclosed at temperature between 55 ^{o}C to 63 ^{o}C (see page 3, lines 25-26). An effective amount is administered (page 21, line 31) and 12,500 grams is generated, (page 18, line 18).

AU-A-63136/94 (AU) teaches a colostrum product prepared by a method comprising subjecting colostrum to ultra-filtration to obtain an ultra-filtered colostrum retentate, and recovering the retentate, wherein said product is further subjected to a spray drying process. Note page 1 and claim 1 of the this cited patent. Also the colostrum is subjected to bacterial reduction using centrifugation. Note page 1, claim 2. The colostrum is also subjected to heat, note page 4, line 31. Temperatures used and

disclosed for preparing the colostrum are less than 64 ^{o}C and 72 ^{o}C, see page 6, line 15. The colostrum product contains 71.0 % protein, see Table 3.

Clarke et al teach colostrum contains IGF-1 (insulin growth factor-1) proteins, at column 44, 1rd paragraph, lines 11-12. Further, improved body composition and condition is achieved by the presence of IGF-I levels, administered via colostrum note page 44, lines 1-20. Also reduction of muscle damage during exercise by enhancing healing is disclosed, see page 44-45, all lines and page 46, lines 22-35. Further, it is also disclosed that colostrum is a food and promotes healing of the body composition by ridding the body of toxins and reducing fatigue, note page 51 , lines 1-3. Also improved exercise performance is noted in that it is disclosed that physical stress from exercise causes fatique, infection, etc. and colostrum reduces these symptoms and infections, note column 44, second paragraph, lines 6-10. Clarke et al also teach that the effectiveness of colostrum depends on how it is produced or processed, note column 15, lines 6-8.

Ballard et al teach reconstituting dry samples in a buffered saline, note column 26, lines 65-67. Colostrum is disclosed at column 27, line 55.

Claims differ from WO 97/16977 (WO) in that a spray drying step and changing physical work capacity of the subject upon administering the prepared colostrum are not specifically disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the above teachings as disclosed to spray dry to prepare the colostrum and then administer it to a subject to change the physical work

capacity of the subject disclosed by WO since AU, Clarke et al and Ballard each teach preparing colostrum and AU specifically teaches success for such colostrum preparations using spray drying and Clarke et al teach that colostrum can be processed to enhance the presence of proteins and can include IGF-1. Ballard et al specifically teach preparing colostrum to include a reconsitution step. Therefore, to include other steps in the process of preparing colostrum as disclosed by WO is clearly within the skill of an ordinary artisan. WO specifically states that other steps may also be included in the process of their disclosure, note page 3, lines 30-32.

Each of the process steps of spray drying and reconstituting colostrum not specifically disclsoed by WO can be performed as recongized by the cited prior art on colostrum with successful expected results. The temperature of centrifugation and heating steps is clearly taught by WO as discussed above. To remove bacteria or reduce bacteria by centrfugation to increase proteins in the colostrum product is clearly taught as well. Ultrafiltration is clearly disclosed. Spray drying is also a recognized step in the art to be performed with success when desired.

Thus, there is no unexpected successful result obtained by Applicants claimed method of preparation. The colostrum would have been expected to have IGF-1 factor and hence would have been expected to be successful for changing physical work capacity of a subject upon adminsitering it to a subject as a food. Each of these claim features are disclosed by the cited prior art as discussed above. Clarke et al recognized that resistive exercise can be changed by reducing infection and fatigue via administering colostrum as a food to a subject in need of such change or repair.

Colostrum having IGF-1 clearly would have provided successful results and based upon the teachings of the cited prior art one of skill would have been motivated to administer it to a subject in need of changing work capacity.

To select for specific effective amounts of at least 0.5 g/g/day or from 1 to 10 g/kg/day for a subject to ingest is within the skill of an ordinary artisan. WO teaches that more than these dosage amounts are obtained from the process, therefore, the dosages as claimed are certainly available in the cited prior art and to determine effective amounts from what is available is well within the purview of a skilled artisan. In the absence to the contrary the claims are rendered *prima facie* obvious.

Response to Arguments

Applicant's arguments filed June 2, 2008, have been fully considered but they are not persuasive. The amendments filed June 2, 2008, have overcome the rejection under 35 USC 112, second paragraph. With respect to the arguments directed to the rejection made under 35 USC 103, it is noted that the present claimed invention is directed to a method of improving physical work capacity via administering a prepared colostrum fraction and hence product by process type claims are presented. The processes as presently claimed occur without a detectable change in plasma IGF-1, however, there is not detectable change in plasma IGF-1 disclosed by the prior art because it is silent in the prior art.

The prior art discloses in combination the same steps as claimed to prepare the colostrum fraction and the same is administered to a subject. The presently claimed invention preserves a combination of components because of the way it is prepared and

the prior art demonstrates the desire to preserve the same components. Thus, there is an expectation of successful results upon administering a colostrum fraction to a subject to improve the physical work capacity of the subject, and as disclosed by Clark et al. Clark et al clearly suggest that colostrum can improve the physical work capacity of a subject.

The argument that none of the cited prior art references provides any motivation or reasoning for isolating the claimed colostrum fraction is noted, however, the cited prior art clearly teach the same steps as claimed by Applicant for isolating the colostrum fraction and hence at least a similar product as claimed would be expected to be provided by the cited prior art and Clark et al recognize that a colostrum fraction improves physical work capacity or at least suggests an improvement.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Clark et al is combined with other cited prior art to show that improvement of physical work capacity in a subject has been associated with a colostrum fraction. The method steps of preparing the colostrum fraction are disclosed by the primary reference and other secondary references of record. Thus, although point 9 of the affidavits of record is noted, it is not persuasive since it is irrelevant to the rejection and the art applied because it does not directly teach away from the cited prior art.

The claimed retentate fraction is at least suggested by the cited prior art because the cited prior art teach preparing such fraction using identical isolation techniques well recognized in the cited prior art and also teach ingesting the colostrum fraction. These steps are all disclosed by the cited prior art and one of skill in the art would have been motivated to ingest at least a similar fraction as claimed and given the teachings of Clark et al would have expected successful results for improving physical work capacity because the colostrum fraction will contain the same components as the claimed colostrum fraction since it is disclosed to be prepared the same way. Upon preparing a colostrum fraction as disclosed by the cited prior art, the colostrum will contain the same components and one of skill would have expect successful results for changing physical work capacity by improving the same in a subject.

Clark et al do teach or at least suggest that colostrum's many immune factors demonstrate reduction in the occurrence and severity of numerous types of infections caused by physical exertion during exhaustive workouts, note page 44, lines 22-23. Further, they teach that IGF-1,which is contained in colostrum fraction, improves body condition, note page 44, lines 3. Therefore, the argument that Clark et al do not teach or suggest improving physical work capacity is not persuasive.

Finally, the cited prior art does not teach that there is an increase in circulating IGF-1 levels either, and Clark et al clearly teach, or at least suggest, maintaining the IGF-1 levels and not increasing IGF-1. Thus, it is maintained that no unexpected successful results have been obtained or illustrated by Applicant's claimed invention. Each of the factors for supporting an obviousness rejection have been set forth and

these factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

All claims fail to be patentably distinguishable over the state of the art discussed above and previously cited on the PTO-892 and/or PTO-1449 Forms of record. Therefore, the claims are properly rejected.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/DKW/
Deborah K. Ware
Art Unit 1651

/David M. Naff/
Primary Examiner, Art Unit 1657